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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 10/597,298 | 07/19/2006 | Giorgio Caravatti | 33612-US-PCT | 8934 |
| 1095 | 7590 | 09/02/2009 | EXAMINER | |
| NOVARTIS | | | MOORE, SUSANNA | |
| CORPORATE INTELLECTUAL PROPERTY | | | ART UNIT | PAPER NUMBER |
| ONE HEALTH PLAZA 104/3 | | | 1624 | |
| EAST HANOVER, NJ 07936-1080 | | | | |
| | | MAIL DATE | DELIVERY MODE | |
| | | 09/02/2009 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/597,298 | CARAVATTI ET AL. |
| | Examiner | Art Unit |
| | SUSANNA MOORE | 1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 and 13 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-10 and 13 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/19/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

There are 11 claims pending and 11 under consideration. Claims 1-9 are compound claims. Claim 10 is a composition claim. Claim 11 is a process of making claim. This is the first action on the merits. The application concerns some pyrrolo[3,2-d]pyrimidine compounds, compositions, synthesis, and uses thereof.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Substituted Pyrrolo[2,3-d]pyrimidines For Treating Proliferative Diseases.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/19/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 9 is objected to because of the following informalities: claim 9 is a substantial duplicate of claim 1 as the only difference is a statement of intended use, which is not given material weight. Note *In re Tuominen* 213 USPQ 89. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Throughout these claims, Applicants employ the terms “substituted or unsubstituted alkyl,” “substituted and unsubstituted aryl,” “substituted or unsubstituted heteroaryl,” etc. The specification fails to list the intended substituents. What other substituents does Applicant claim? Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term.

Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Claims which depend from claim 1 which fail to remedy the deficiency of claim 1 are also rejected for the reasons set forth herein.

Regarding claims 1-6, the phrase “X is either not present or” is vague. If X is not present then R1 cannot be attached to formula (I). The Examiner suggests rewording said phrase to “X is either a bond or” to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 and 13 are rejected under 35 U.S.C. 102(a and e) as being anticipated by

Bold et. al. (US 7323469 B2).

The reference claims the following compound: ((R)-1-phenyl-ethyl)-[6-(4-piperazin-1-ylmethyl-phenyl)-7H-pyrrolo[2,3-d]- pyrimidin-4-yl]-amine, in claim 1 of the '469 patent, which is the same compound claimed in claim 7 of the instant Application. Claim 2 in the '469 patent is drawn to pharmaceutical compositions. The process is taught in columns 10-11 of the '469 patent. Thus, claims 1-10 and 13 are anticipated by Bold et. al.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claims 1-10 and 13 are rejected under 35 U.S.C. 102(a and e) as being anticipated by **Bold et. al. (US 7244729 B2).**

The reference teaches the following compound: ((R)-1-phenyl-ethyl)-[6-(4-piperazin-1-ylmethyl-phenyl)-7H-pyrrolo[2,3-d]- pyrimidin-4-yl]-amine, is found in column 30, in the table, example 30 in the '729 patent, which is the same compound claimed in claim 7 of the instant Application. Column 16, line 7, is drawn to pharmaceutical compositions. The process is taught in columns 9-11 of the '729 patent. Thus, claims 1-10 and 13 are anticipated by Bold et. al.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-10 and 13 are rejected under 35 U.S.C. 102(a and e) as being anticipated by Ball et. al. (US 20050038048 A1, application 10493787).

The reference teaches the following compound: ((R)-1-phenyl-ethyl)-[6-(4-piperazin-1-ylmethyl-phenyl)-7H-pyrrolo[2,3-d]- pyrimidin-4-yl]-amine, in the table on page 7, left-hand column, example 6, of the '048 publication, which is the same compound claimed in claim 7 of the instant Application. The compositions are taught on page 5, paragraph 0081. The process is taught on page 4. Thus, claims 1-10 and 13 are anticipated by Bold et. al.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claims 1-10 and 13 are rejected under 35 U.S.C. 102(a and e) as being anticipated by Bold et. al. (US 7390805 B2).

The reference teaches the following compound: ((R)-1-phenyl-ethyl)-[6-(4-piperazin-1-ylmethyl-phenyl)-7H-pyrrolo[2,3-d]- pyrimidin-4-yl]-amine, in columns 25-26, in the table, example 14, of the ‘805 patent, which is the same compound claimed in claim 7 of the instant Application. The compositions are taught in column 15, lines 22-25. The process is taught in columns 9-10 of the '729 patent. Thus, claims 1-10 and 13 are anticipated by Bold et. al.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7323469 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because see the 102(e) rejection above.

Claims 1-10 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7244729 B2. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the compound in claim 4, column 62, lines 53-55,

{6-[4-(4-methyl-piperazin-1-ylmethyl)-phenyl]-7H-pyrrolo[2,3-d]pyrimidin-4-yl}-((R)-1-phenyl-ethyl)-amine;

, is a homologue of the compound listed in claim 7, ((R)-1-phenyl-ethyl)-[6-(4- piperazin-1-ylmethyl-phenyl)-7H-pyrrolo[2,3-d]pyrimidin-4-yl]-amine. The only difference is the methyl substituent on the piperazinyl group. Since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states “Compounds which are... homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). Also, note *In re Magerlein*, 202 USPQ 473; *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, 137 USPQ 548.

This is just one example of the many compounds which renders the instant application obvious.

Claims 1-10 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7390805 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound in claim 1, column 61, lines 41-43, (3-methyl-benzyl)-[6-[4-(4-methyl-piperazin-1-ylmethyl)-phenyl]-7H-pyrrol- o[2,3-d]pyrimidin-4-yl]-amine, is a homologue of the compound listed in claim 7, ((R)-1-phenyl-ethyl)-[6-(4- piperazin-1-ylmethyl-phenyl)-7H-pyrrolo[2,3-

dJpyrimidin-4-yl]-amine. The only differences are a) the methyl substituent on the piperazinyl group and b) the methyl on the phenyl ring, i.e. 3-methylbenzyl. Since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states “Compounds which are... homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). Also, note *In re Magerlein*, 202 USPQ 473; *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, 137 USPQ 548.

This is just one example of the many compounds which renders the instant application obvious.

Claims 1-10 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24, 26 and 27 of copending Application No. 10493787. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specie claimed, {6-[4-(4-ethyl-piperazin-1-ylmethyl)-phenyl]-7H-pyrrolo[2,3-d]pyrimidin-4-yl)-((R)-1-phenyl-ethyl)-amine is different only by the ethyl substituent on the piperazinyl ring. As outlined above in the 102(e) art rejection, there is a guidepost with an unsubstituted piperazinyl ring, ((R)-1-phenyl-ethyl)-[6-(4-piperazin-1-ylmethyl-phenyl)-7H-pyrrolo[2,3-d]- pyrimidin-4-yl]-amine. The ‘787 application is drawn to methods of intended use with the ethyl compound, however, a restriction requirement was not done in either case. Thus, claims drawn to compounds and to a method of intended use of said compounds are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624